510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number: k040379

B. Purpose For Submission:

Premarket Notification 510(k) of intention to manufacture and market the Randox Laboratories Ltd. Immunoassay Control, Levels I, II, III.

C. Analyte: Thirty-three different analytes listed in J (3) below.

D. Type of Test: Quality Control Material

E. Applicant: Randox Laboratories Ltd.

F. Proprietary and Established Names: Randox Immunoassay Control Levels I, II and III

G. Regulatory Information:

1. Regulation section: 21 CFR §862.1660, Multi-Analyte Controls, all kinds (assayed and unassayed).

2. Classification: Class I

3. Product Code: JJY

4. Panel: 75 Chemistry

H. Intended Use:

1. Intended use(s):

   This product is intended for in vitro diagnostic use in the quality control of Immunoassays on clinical chemistry and Immunoassay systems.

2. Indication(s) for use:

The Randox Laboratories Ltd. Immunoassay Controls (Levels I, II, and III) are based on lyophilized human serum and have been developed for the control of both accuracy and precision in clinical chemistry applications, particularly Immunoassay analysis. The control materials are available at three constituent concentrations. Each level is available in a 5 ml final re-constituted volume.

The Randox Assayed Immunoassay Controls should only be used by suitably qualified laboratory personnel under appropriate laboratory conditions.

3. Special condition for use statement(s):
   Prescription use

4. Special instrument Requirements:
   The names of the specific analyzers are listed in the package insert.

I. Device Description:

The Randox Immunoassay Controls are human based lyophilized sera which are supplied at levels I, II and III. Each 5 ml vial of lyophilized serum is reconstituted with exactly 5 ml of distilled water at +20 to 25° C. This material is inherently free from human based infective sources of human immunodeficiency Virus (HIV 1, HIV 2) antibody, hepatitis B surface antigen, and hepatitis C virus antibody. Nevertheless it should be handled and disposed of with the same attention afforded to human samples.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Bio-Rad Immunoassay Control Serum

2. Predicate K number(s):
   k894252

3. Comparison with Predicate:

The Randox Immunoassay Controls are equivalent to the Bio Rad Lyphochek® Immunoassay Plus Control, Levels 1, 2, and 3 previously cleared under (k894252). The table below lists the similarities and differences between the Predicate and Proposed device.

Characteristic	**Proposed Device: Randox Immunoassay Control, Level I, II, and III (k040379)**	**Predicate Device Bio-Rad Lypochek® Immunoassay Plus Control, Levels 1, 2, and 3 (k894252)**
Intended Use	This product is intended for in vitro diagnostic use in the quality control of Immunoassays on clinical chemistry and Immunoassay systems.	Similar
Matrix	Lyophilized human sera with added constituents.	Similar
Number Of Levels	Levels I, II, and III	Similar
Open Vial Stability	Reconstituted serum is stable	Similar

	for 7 days at 2 to 8°C if kept capped in original container and free from contamination or 4 weeks frozen once at -20° C. The P.S.A. in these sera will be stable for 2 days at +2 to +8° C.	
Unopened Vial Stability	Unopened vials stored at 2 to 8° C are stable through the expiration dated printed on the individual vials.	Similar
Product Description	The Randox Laboratories Ltd. Immunoassay Controls (Levels I, II, and III) are based on lyophilized human serum and have been developed for the control of both accuracy and precision in clinical chemistry applications, particularly Immunoassay analysis. The control materials are available at three constituent concentrations. Each level is available in a 5 ml final re-constituted volume.	Similar
Precautions	Is intended for in vitro diagnostic use only by trained personnel. This material is inherently free from human based infective sources. Nevertheless it should be handled and disposed of with the same attention afforded to human samples.	Similar
Parameters	Contains the following 33 Analytes: AFP, B2M, CA125, CA15-3, CA19-9, CARBAMAZEPINE, CEA, CORTISOL, DHEA-S, DIGOXIN, FERRITIN, FOLATE, FSH, GROWTH HORMONE, HCG, IGE, LH, ESTRADIOL, PHENYTOIN, 17-OH-PROGESTERONE,	Similar

	PROGESTERONE, PROLACTIN, PSA FREE, PSA TOTAL, FREE T3, TOTAL T3, FREE T4, TOTAL T4, TESTOSTERONE, THEOPHYLLINE, TSH, VALPROIC ACID, VITAMIN B12	

K. Standard/Guidance Document Referenced (if applicable):

FDA guidance "Points to Consider Guidance Document on Assayed and Unassayed Quality Control Materials".

L. Test Principle: NA

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. *Precision/Reproducibility:* *NA*

    b. *Linearity/assay reportable range:* *NA*

    c. *Traceability (controls, calibrators, or method):*

    Each batch of Immunoassay control is submitted to a number of reference Laboratories and values are assigned from a consensus of results obtained by these laboratories. A value (Mean) has been assigned to this lot of control at Randox Laboratories Ltd using an ELISA method. The package insert lists the target values and ranges applicable to each analyte and each instrument.

    Reconstituted serum is stable for 7 days at 2 to 8°C if kept capped in original container and free from contamination or 4 weeks frozen once at -20° C. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial. The PSA will remain stable for 2 days at +2 to +8° C.

    d. *Detection limit:* *NA*

    e. *Analytical specificity:* *NA*

    f. *Assay cut-off:* *NA*

2. Comparison studies:
    a. *Method comparison with predicate device:* *NA*

b. Matrix comparison: *NA*

3. Clinical studies:
   a. Clinical sensitivity: *NA*

   b. Clinical specificity: *NA*

   c. Other clinical supportive data (when a and b are not applicable):NA

4. Clinical cut-off: NA

5. Expected values/Reference range: NA

N. Conclusion:

The submitted material in this premarket notification is complete and supports a substantial equivalence decision.